UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,224	07/01/2003	Phillip R. Cunningham	WSV-2597	5754

959 7590 12/28/2004

LAHIVE & COCKFIELD, LLP.
28 STATE STREET
BOSTON, MA 02109

EXAMINER	
AKHAVAN, RAMIN	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

12/27/04 M

Office Action Summary	Application No.	Applicant(s)	
	10/612,224	CUNNINGHAM, PHILLIP R.	
	Examiner	Art Unit	
	Ramin (Ray) Akhavan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of a preliminary amendment, including submission of new claims 29-36. Claims 1-36 are pending and under consideration in this action.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121 (each invention designated with a Roman numeral):

I. Claims 1-22, drawn to plasmids and cells containing said plasmids, designated in class 435, subclass 320.1.

II. Claims 29-32, drawn to functional mutant ribosomes, designated in class 530, subclass 350.

III. Claims 33-34, drawn to drug candidates, designated in class 514, subclass 2.

IV. Claims 35-36, drawn to genomics databases, designated in class 707, subclass 104.

V. Claims 23-26, drawn to methods of identifying functional mutant ribosomes, designated in class 435, subclass 6.

VI. Claims 27-28, drawn to methods of identifying drug candidates, designated in class 435, subclass 7.2.

The claims encompass 6 biologically and patentably distinct inventions and a search for one invention would not necessarily be coextensive with any other group. For ease of organization the analysis of the grounds for restriction will be directed to the products (Set 1: Groups I-IV) first, followed by the inventions directed to processes (Set 2: Group V-VI).

Inventions in Groups I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Group I is directed to plasmids and cells containing the same, where plasmids have the correlative function of expression and encoded protein or transforming a host cell. Therefore, plasmids/cells are not related by either structure or function to functional mutant ribosomes (Group II), drug candidates (Group III) or a genomics database (Group IV). It follows, that neither of Groups I-IV is necessarily capable of use with any of the other members of Set 1. Clearly, plasmids/cells have a different function, as compared to ribosomes (functioning in translation), drug candidates (having therapeutic effects) or databases (storing information). Because the inventions comprise biologically distinct structures and functions, a search for one group would not necessarily yield an invention from another group. For example, in searching for expression plasmids or cells, one would not discover a genomic database, a drug candidate or a functional ribosome structure.

In addition, Group V and VI are unrelated inventions. Each process has a biologically and patentably distinct outcome, i.e. identifying a functional mutant ribosome versus identifying a drug candidate. A method of identifying one compound cannot be used concomitantly with a method for identifying another compound, where each compound is drawn to a distinct structure with an attendant biologically and patentably distinct function (i.e. ribosome functioning in translation of proteins versus a drug candidate which would confer a therapeutic effect). Furthermore, because each process could be used independent from the other and with a distinct objective, searching for one process would not necessarily be coextensive with the other.

Searching the nonpatent literature for an assay to identify one compound would not necessarily yield an assay to identify a totally distinct compound.

Each of Groups II-III is unrelated as compared to either of Groups V-VI. Again, each product (Groups II-III) is directed to structurally and functionally distinct inventions. As such an assay for identifying a particular product involves a materially different function or outcome. For example, a genomic database functions in data storage and retrieval, while process for identification of functional mutant ribosomes or drug candidates function in selecting a particular compound, each with a particular function. Similarly, a drug candidate and functional mutant ribosome, while being identified through the processes of either Group V or VI, are not capable of use with such processes insofar as the products do no share any structural/functional with processes. By definition the processes have a different functionality compared to the products they identify. It follows, that searching for products would not necessarily yield processes for identifying such products. Functional mutant ribosomes can be identified through methods having nothing to do with the plasmids/cells used in the process of identification. For example, the mutant functional ribosomes can be maintained in a water-soluble solution which can be encapsulated in a liposome formulation, along with expression elements encoding desired target proteins. As such, the functionality of the ribosomes can actually be assayed without a plasmid-transformed cell.

Inventions in Groups I and Groups V-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case plasmids can be used to produce recombinant proteins either on the laboratory or large scale.

Species Election

This application contains claims directed to the following patentably distinct species of the claimed invention: Claims 4-6 and 15-17 drawn to SEQ ID NOs: 24-159. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (i.e. a single species) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper

Conclusion

The claims encompass six separate inventions as well as 136 separate species.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ramin (Ray) Akhavan whose telephone number is 571-272-0766. The examiner can normally be reached on Monday- Friday from 8:00-4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully submitted,

Ray Akhavan/AU 1636